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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,014	03/23/2001	Bernd Scholler	6056-000039	8518
27572	7590	08/24/2006	EXAMINER	
HARNES, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			LEWIS, AARON J	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 08/24/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/816,014	SCHOLLER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	AARON J. LEWIS	3743	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenke et al. ('373) in view of Behbehani et al. ('952) and Froehlich et al. ('146).

As to claim 1, Gruenke et al. disclose a procedure for the control of a respirator device, in which one can set at least two different levels (col.6, lines 30-34) for a breathable gas supply, comprising: capturing at least three parameters by measurement technique (col.20, lines 26-53); evaluating the at least three parameters (col.20, line 62- col.22, line 36); and wherein the respirator device is controlled in an adaptive manner such that time-wise evolution of the at least three parameters maintain, at most, a predefined maximum difference from the typical evolution patterns, and wherein the at least three parameters include respiratory pressure (1806), respiratory flow (1802) and respiratory impedance (col.20, lines 47-53); and wherein a CPAP respirator treatment is carried out (col.6, lines 30-34 and col.12, lines 41-42).

To the extent, if any that Gruenke et al. lack the step of capturing the parameter of respiratory impedance (inasmuch as Gruenke et al. expressly disclose the derivation of respiratory admittance which is the inverse of respiratory impedance), resort is had to Behbehani et al., in a CPAP device, which teach the capturing the parameter of

respiratory impedance for the purpose of determining an estimate of the degree of obstruction of the airway of a patient's respiratory system (col.2, lines 10-20) so that a proper amount of CPAP pressure may be calculated and applied to a patient's airway in order to maintain airway patency.

It would have been obvious to modify the method of respirator control of Gruenke et al. to capture the parameter of respiratory impedance by any well known method including a forced oscillation technique because it would have provided an estimate of the degree of obstruction of the airway of a patient's respiratory system so that a proper amount of CPAP pressure may be calculated and applied to a patient's airway in order to maintain airway patency as taught by Behbehani et al..

The difference between Gruenke et al. as modified by Behbehani et al. and claim 1 is the step of based on a pattern recognition, analyzing at least one characteristic of the respirator device selected from the group consisting of defect, reduced performance, leak in the region of the apparatus or in the region of a hose connection.

Froehlich et al. (col.8, lines 41-59) in a CPAP respirator, teach based on a pattern recognition, analyzing at least one characteristic of the respirator device selected from the group consisting of defect, reduced performance, leak in the region of the apparatus or in the region of a hose connection. More specifically, Froehlich et al. (col.8, lines 41-59) teach the steps of recognizing and analyzing a pattern of pressure and flow of breathable gas that is consistent with a leak or disconnection of the supply hose and subsequently placing the ventilator in a standby mode for the purpose of preventing the wasting of breathable gas.

It would have been obvious to further modify the CPAP respirator of Gruenke et al. to include a means for recognizing and analyzing a pattern of pressure and/or flow of breathable gas consistent with that of a leak or disconnection and subsequently shutting the ventilator down responsive thereto because it would have prevented wasting of breathable gas as taught by Froehlich et al..

As to claim 2, Behbehani et al. teach an existing pressure level for breathing support is overlaid, at least temporarily, with a stimulating stream oscillating at a defined frequency (see steps #3 and #5 of flow chart illustrated in fig.1).

As to claim 3, Gruenke et al. as modified by Behbehani et al. (col.21, lines 38-45 of Gruenke et al.) teach a selection of the respective pressure amplitude (i.e. increase, decrease, maintain pressure as disclosed in col.21, lines 43-45 of Gruenke et al.) after a selective evaluation of an oscillatory pressure amplitude, occurring with a frequency of a stimulating stream in the air delivery of a patient (forced oscillation technique of respiratory impedance determination in Behbehani et al.).

As to claims 5 and 6, Gruenke et al. (fig.19) disclose at least one physical electrical signal is evaluated during the pattern recognition.

As to claim 7, Gruenke et al. (col.21, lines 8-10) disclose the calculated admittance to determine the "best fit" for a given treatment profile. In the process of arriving at the "best fit", a number of treatment profiles would be eliminated in favor of the "best fit". The treatment profiles that are eliminated are readable upon the recited class of errors in claim 7 because they are not found to be the proper treatment profile.

As to claim 8, Behbehani et al. teach an oscillating signal being evaluated using the forced oscillation technique of determining airway impedance (col.2, lines 10-20).

As to claim 9, Gruenke et al. disclose a static pressure signal (1806) being evaluated.

As to claim 10, Gruenke et al. disclose pressure variation being evaluated (col.21, lines 40-45), that is, the pressure of the CPAP air being delivered to a patient.

As to claim 11, Gruenke et al. disclose the flow signal (1802) being evaluated (col.20, lines 26-33 and fig.19).

As to claim 12, Gruenke et al. disclose a signal proportional to at least one of the flow signal (1802) and to a pressure-dependent signal (1806) is evaluated.

As to claim 13, Gruenke et al. disclose an electrical drive parameter of the compressed gas supply is evaluated (col.25, lines 50-62).

As to claims 14-16, Gruenke et al. (fig.19) illustrate distinctive form features of each of pressure, flow and admittance/impedance by their individual plots. The plotting of a flow data, pressure data and admittance/impedance data to their individual plots is exemplary of a class assignment being carried out.

### ***Response to Arguments***

3. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant methods for controlling a respirator device.
5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
AARON J. LEWIS  
Primary Examiner  
Art Unit 3743

Aaron J. Lewis  
August 21, 2006